REMARKS

As a preliminary matter, please note the extension of time of three (3) months included with this response.

The claims have been amended. However, no claim fees are due as no new claims have been added. Support for the amendments can be found, for example, at: page 20, lines 3-5; page 31, lines 6-10; page 31, .line 19; Page 1, line 5; Page 9, last line; Page 10, line 10; Page 11, line 2; Page 12, line 15; Page 3, line 35; Page 4, lines 4-6; Page 4, lines 30-33; Page 8, lines 11-32; Page 20, lines 33-37.

Claims 2, 7-9, 12-32, 44-45, 56, 49-51, 56-81, 88-97, 101, 103-108, 118-122, 124, and 130-131 are currently pending in the application.

Claims 2, 7-9, 12-32, 44-45, 49-51, 56, 63-81, 88-97, 101, 103-108, 118-122, 124, and 130-131 continue to be rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. (4,765,989) in view of Stevens et al (5,897,874).

The rejection is traversed on the basis that Wong and Stevens are not properly combinable and that the combination does not support obviousness in any event, particularly in light of the claims as now amended. Applicants' arguments from their response dated August 19, 2003 are incorporated by reference in this regard.

As a preliminary point, Applicants note that the tableting aid in the instant claims is selected from lactose, xylitol, microcrystalline cellulose, HPC, MC, and HPMC. See claim 2 as currently amended. Magnesium stearate, which was particularly singled out by the Examiner as a tableting aid in Wong, is not part of the aforementioned group. Thus it would not be obvious to administer the aforementioned specific tableting aids disclosed in Wong based on a disclosure of magnesium stearate.

Further, claim 2 requires that the tableting aid is at least 20 wgt % of the water-swellable composition. Stevens, in direct contrast (see column 4, starting at line 32), teaches that his expandable excipients may only include "minor" amounts of formulation adjuncts, as follows:

> ...Wetting agents (e.g. sodium lauryl sulphate) may be included, usually in amounts up to 2% by weight. Flow agents such as magnesium

> stearate and fumed silica may be added, generally in amounts up to 1% by weight. Water-soluble materials such as sugars or other carbohydrates may be included, generally in in amounts of up to 10% by weight. Wicking agents such as those materials already mentined as disintegrants (e.g., microcrystalline cellulose) may be included if necessary to enhance the speed of water uptake, preferably in amounts up to 10% by weight. [Column 4, lines 33 et seq.]

Clearly, one would not include Applicants' tableting aid in an amount of at least 20% based on Stevens which discloses including his excipients in much smaller amounts.

Further, as described in the application (and highlighted in Applicants' previous response), one of the problems that results from using highly swelling water swellable materials is that highly swelling materials are difficult to compress to a hardness suitable for use. See page 30, lines 31-33 of the application. The inventors solved the problem by combining swelling agents having a high degree of swelling with a particular tableting aid to achieve both good release and good tablet strength. Page 30, line 34 – Page 31, line 5. Applicants' solution is not obvious over the combination suggested by the Examiner. As previously mentioned, Claim 2 requires a controlled release dosage form with a drug-containing composition and a water-swellable composition, the swelling ratio for the water-swellable composition being ≥ 3.5, and the tablet strength being ≥ 3 Kp/cm^2. Applicants note that the claims therefore require a specific combination of a minimum swelling ratio and a minimum tablet strength. Neither this combination of both a high degree of swelling and good strength, nor a way to achieve it, is suggested by the combination of Wong and Stevens. This is demonstrated by the Wong et al examples which disclose a water swellable composition comprising poly(ethylene)oxide having a molecular weight of 5,000,000 or 6,000,000 and sodium chloride. As demonstrated in the (previously submitted) Declaration of Scott McCray, this type of water swellable composition does not meet the claim limitation that the water swellable composition have the aforementioned swelling ratio of at least 3.5 as required by the claim. There is no discussion otherwise in Wong et al. regarding the desirability of using highly swelling water swellable materials, the difficulty in compressing tablets containing such

materials to a hardness suitable for use, or that the water swellable composition should contain a particular tableting aid to solve the problem.

As an additional point, Applicants' claims now require the claimed dosage form to be a tablet. Stevens et al. do not disclose a tablet. The considerations for formulating a capsule, as in Stevens, are very different from those for formulating a tablet, as reviewed in Applicants previous response. Because Stevens is concerned with a capsule, there is no recognition in Stevens et al. that, to achieve the good tablet properties required by Applicants, the water swellable composition must be formulated to combine both a swelling agent with a high degree of swelling and a tableting aid. One of ordinary skill in the art interested in making a tablet would undoubtedly dismiss Stevens out of hand as irrelevant because it simply doesn't deal with tablets or any way of formulating tablets having high swelling ratios and high strength like those claimed by Applicants.

Claim 57 continues to be rejected over Wong et al. in view of Stevens et al in further view of the Jim Kling article. Kling was cited for its teaching of Viagra® as a drug for hypertension or erectile function. Wong and Stevens appear to have been cited for the reasons set forth by the Examiner in rejecting the remaining claims. Applicants note that claim 57 depends directly from claim 2. The rejection is traversed on the basis that the combination of Wong and Stevens is fatally defective for the reasons advanced above in Applicants discussion of claim 2 in relation to Wong and Stevens, and Applicants' comments in that respect are incorporated herein by reference. The Kling article simply discloses Viagra®. It does nothing otherwise to remedy the fatal defects of Wong and Stevens.

Claims 2, 7-9, 12-32, 44-45, 49-56, 63-81, 88-97, 101, 103-108, 118-122, 124, and 130-131 were rejected under 35 USC §103(a) as being unpatentable over Wong in view of Park, US 6,271,278. In making the rejection, the Examiner appeared to be citing Wong for substantially the same teachings as those cited by the Examiner when making the rejections discussed above. The Examiner specifically noted that "Wong does not teach instant parameters and instant swelling agent". The Examiner reviewed the teachings of Park which are related to a hydrogel composition having fast

swelling and high mechanical strength. The Examiner took the position that it would have been obvious to combine the teachings of Wong and Park:

> It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Wong et al and Park et al and instant swelling capacity (ratio) and swelling agents. One would be motivated to do so since park discloses that a fast swelling hydrogel and superswelling is important for controlled oral dosage forms. Further, motivation to do so being that Park discloses that the superabsorbent hydrogel is an improvement over the prior art's hydrogels since it not only possess super swelling capacity but is also has increased mechanical strength by using instant selling agents. Therefore, one would be motivated to add Park's hydrogel into Wong's second composition for the stated advantages. Further one would expect similar results, since Park states the hydrogel may be used as a platform in controlled dosage forms. Therefore, Park's hydrogel would fit directly into Wong's second expandable composition since both are designed for the same purpose of swelling in contact with biological fluids and thus releasing the active. [Office Action, paragraph bridging pages 11 and 12]

The rejection is traversed in light of the claims as now amended. The deficiencies of Wong have been discussed above and those comments are incorporated by reference. Park simply relates to a novel swellable hydrogel composition. The material is stated to be formed in part from at least one ethylenically unsaturated monomer such as acrylic or methacrylic acid or a salt or ester thereof, a crosslinking agent, and particles of a disintegrant. Thus Park is concerned with a swelling material different from those now specifically required by Applicants' claims, i.e., sodium starch glycolate and/or croscarmellose sodium. One of ordinary skill in the art would not find Applicants' invention obvious by substituting Park's hydrogel into Wong's second composition as stated by the Examiner because, *inter alia*, Applicants' claims require a different sweller material that Park is not concerned with. In different words, Applicants' claims, requiring as they do sodium starch glycolate and/or croscarmellose sodium as the swelling agent, cannot be obvious over a reference that is focused on a completely different swelling agent.

Claim 57 was rejected under 35 USC §103(a) as being unpatentable over Wong in view of Park and further in view of the Kling article. Wong and

Park were cited as teaching delivery devices containig expandable excipients. Kling was cited for its teaching of Viagra®.

The rejection is traversed on the basis that the claims, as amended, are not obvious over Wong, Park, and Kling. Wong and Park are defective for the reasons previously noted. The mere disclosure of Viagra® by Kling in no way remedies those deficiencies.

It is accordingly respectfully requested that all rejections be withdrawn. In view of the foregoing comments and amendments, this case is believed to be in condition for allowance, and a Notice of Allowance is courteously solicited.

Respectfully submitted,

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